

DATA PACKAGE BEAN SHEET

Date: 11-Apr-2019

Page 1 of 2

Decision #: 549240

DP #: (451580)

PRIA

Parent DP #:

Submission #: 1031753

E-Sub #: 37278

*** Registration Information ***

Registration: 93167-EUP-E -

Company: 93167 - OXITEC LTD.

Risk Manager: RM 94 - Alan Reynolds - 703-605-0515 Room# PY1 S-8937

Risk Manager Reviewer: Eric Bohnenblust EBOHNEN

Sent Date:

PRIA Due Date: 01-Nov-2019

Edited Due Date:

Type of Registration: Experimental Use Permit - Section

Action Desc: (B620) New Active Ingredient; Experimental Use Permit application; NON-FOOD USE INCLUDING

Ingredients: 006002, Tetracycline-repressible Transactivator Protein Variant (tTAV) protein and the genetic n

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 10-Apr-2019

Due Back:

DP Ingredient: 006002, Tetracycline-repressible Transactivator Protein Variant (tTAV) protein and the genetic n

DP Title: Product Characterization/Human Health

CSF Included: ☐ Yes ☒ No

Label Included: ☐ Yes ☒ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: BPPD / ETB

Last Possible Science Due Date: 02-Oct-2019

Team Name: Biotech Science Team

Science Due Date:

Reviewer Name: Striegel, Wiebke

Sub Data Package Due Date:

Contractor Name:

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

Wiebke,

Please review the attached studies to determine their ability to support the proposed product. Proposed label can be found in Section B of the application in documentum. Let me know if you need anything else.

Eric

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
50698701		Oxitec, Limited (2019) OX5034 Aedes aegypti: Product Identity and Composition, Description of Starting Materials, Production and Formulation Process, Discussion of the Formation of Impurities, Preliminary Analysis, Certified Limits, and Enforcement Analytical Method. Unpublished study. 63p.	830.1700/Preliminary analysis	
50698701		Oxitec, Limited (2019) OX5034 Aedes aegypti: Product Identity and Composition, Description of Starting Materials, Production and Formulation Process, Discussion of the Formation of Impurities, Preliminary Analysis, Certified Limits, and Enforcement Analytical Method. Unpublished study. 63p.	830.1750/Certified limits	
50698701		Oxitec, Limited (2019) OX5034 Aedes aegypti: Product Identity and Composition, Description of Starting Materials, Production and Formulation Process, Discussion of the Formation of Impurities, Preliminary Analysis, Certified Limits, and Enforcement Analytical Method. Unpublished study. 63p.	830.1800/Enforcement analytical method	
50698701		Oxitec, Limited (2019) OX5034 Aedes aegypti: Product Identity and Composition, Description of Starting Materials, Production and Formulation Process, Discussion of the Formation of Impurities, Preliminary Analysis, Certified Limits, and Enforcement Analytical Method. Unpublished study. 63p.	880.1100/Product identity and composition	
50698701		Oxitec, Limited (2019) OX5034 Aedes aegypti: Product Identity and Composition, Description of Starting Materials, Production and Formulation Process, Discussion of the Formation of Impurities, Preliminary Analysis, Certified Limits, and Enforcement Analytical Method. Unpublished study. 63p.	880.1200/Description of starting materials, production and formulation process	
50698701		Oxitec, Limited (2019) OX5034 Aedes aegypti: Product Identity and Composition, Description of Starting Materials, Production and Formulation Process, Discussion of the Formation of Impurities, Preliminary Analysis, Certified Limits, and Enforcement Analytical Method. Unpublished study. 63p.	880.1400/Discussion of formation of impurities	
50698702		Oxitec, Limited (2019) Tetracycline-Repressible Transactivator Protein (tTAV) and Related Genetic Material from OX5034 Aedes aegypti: Request for Waiver from Acute Oral Toxicity Study in Rodents. Unpublished study. 16p.	870.1100/Acute Oral Toxicity	Pass (05-Apr-2019)
50698703		Oxitec, Limited (2019) Tetracycline-Repressible Transactivator Protein Variant (tTAV) and Related Genetic Material from OX5034 Aedes aegypti: Request for Waiver from Acute Inhalation Toxicity Study in Rodents. Unpublished study. 16p.	870.1300/Acute inhalation toxicity	Pass (05-Apr-2019)
50698704		Oxitec, Limited (2019) Tetracycline-Repressible Transactivator Protein Variant (tTAV) and Related Genetic Material from OX5034 Aedes aegypti: Request for Waiver from Primary Eye Irritation Study. Unpublished study. 15p.	870.2400/Acute eye irritation	Pass (05-Apr-2019)
50698705		Oxitec, Limited (2019) Tetracycline-Repressible Transactivator Protein Variant (tTAV) and Related Genetic Material from OX5034 Aedes aegypti: Request for Waiver from Primary Dermal Irritation Study. Unpublished study. 11p.	870.2500/Acute dermal irritation	Pass (05-Apr-2019)
50698706		Oxitec, Limited (2019) Tetracycline-Repressible Transactivator Protein Variant (tTAV) and Related Genetic Material from OX5034 Aedes aegypti: Hypersensitivity Incidents. Unpublished study. 3p.		Pass (05-Apr-2019)

DP#: (451580)

*** Studies Sent for Review ***

Decision#: (549240)

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
50698716		Oxitec, Limited (2019) OX5034 Male-Selecting Trait Decline in a Caged Population of Wild-Type <i>Aedes aegypti</i> . Project Number: SR/00059/ED/2A. Unpublished study. 19p.		Pass (05-Apr-2019)
50698717		Oxitec, Limited (2019) Investigating the Self-Limiting Phenotype and Penetrance of <i>Aedes aegypti</i> , OX5034. Project Number: SR/00017/ED/2A. Unpublished study. 24p.		Pass (05-Apr-2019)
50698718		Liverpool School of Tropical Medicine (LSTM); Liverpool Insect Testing Establishment (LITE) (2019) Evaluation of Insecticide Susceptibility Status of the OX5034 Strain of <i>Aedes aegypti</i> . Project Number: 2018/LITE/013R, 2018/LITE/013, LITSOP011/01. Unpublished study prepared by Oxitec Limited. 72p.		Pass (05-Apr-2019)
50698719		Oxitec, Limited (2019) Quantitative Western Blot Analysis of Expressed Proteins (tTAV and DsRed2) in OX5034 <i>Aedes aegypti</i> Male Adults, Pupae, and Larvae. Project Number: SR0089/EDITION/1/A. Unpublished study. 52p.		Pass (05-Apr-2019)
50698720		Oxitec, Limited (2019) Bioinformatics Analysis for Risks of Allergenicity and Toxicity of Proteins Encoded by the Two Genes Introduced into Genetically Engineered Mosquitoes (<i>Aedes aegypti</i>) Strain OX5034. Unpublished study. 37p.		Pass (05-Apr-2019)
50698721		Oxitec, Limited (2019) Bioinformatics for Predicting Protein Digestibility and Environmental Degradation of OX5034 tTAV and DsRed2 Proteins by Proteases, and Likelihood of these Proteins Crossing a Cell Membrane. Unpublished study. 20p.		Pass (05-Apr-2019)
50698722		Oxitec, Limited (2019) Published Literature Cited in Support of Documents Submitted for an Experimental Use Permit for Tetracycline-Repressible Transactivator Protein Variant (tTAV) and Related Genetic Material from OX5034 <i>Aedes aegypti</i> . Unpublished study. 2540p.	830.1700/Preliminary analysis	Pass (05-Apr-2019)
50698722		Oxitec, Limited (2019) Published Literature Cited in Support of Documents Submitted for an Experimental Use Permit for Tetracycline-Repressible Transactivator Protein Variant (tTAV) and Related Genetic Material from OX5034 <i>Aedes aegypti</i> . Unpublished study. 2540p.	830.1750/Certified limits	Pass (05-Apr-2019)
50698722		Oxitec, Limited (2019) Published Literature Cited in Support of Documents Submitted for an Experimental Use Permit for Tetracycline-Repressible Transactivator Protein Variant (tTAV) and Related Genetic Material from OX5034 <i>Aedes aegypti</i> . Unpublished study. 2540p.	830.1800/Enforcement analytical method	Pass (05-Apr-2019)
50698722		Oxitec, Limited (2019) Published Literature Cited in Support of Documents Submitted for an Experimental Use Permit for Tetracycline-Repressible Transactivator Protein Variant (tTAV) and Related Genetic Material from OX5034 <i>Aedes aegypti</i> . Unpublished study. 2540p.	850.2100/Avian acute oral toxicity test	Pass (05-Apr-2019)
50698722		Oxitec, Limited (2019) Published Literature Cited in Support of Documents Submitted for an Experimental Use Permit for Tetracycline-Repressible Transactivator Protein Variant (tTAV) and Related Genetic Material from OX5034 <i>Aedes aegypti</i> . Unpublished study. 2540p.	850.2200/Avian dietary toxicity test	Pass (05-Apr-2019)

DP#: (451580)

*** Studies Sent for Review ***

Decision#: (549240)

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
50698722		Oxitec, Limited (2019) Published Literature Cited in Support of Documents Submitted for an Experimental Use Permit for Tetracycline-Repressible Transactivator Protein Variant (tTAV) and Related Genetic Material from OX5034 <i>Aedes aegypti</i> . Unpublished study. 2540p.	850.4100/Seedling Emergence and Seedling Growth	Pass (05-Apr-2019)
50698722		Oxitec, Limited (2019) Published Literature Cited in Support of Documents Submitted for an Experimental Use Permit for Tetracycline-Repressible Transactivator Protein Variant (tTAV) and Related Genetic Material from OX5034 <i>Aedes aegypti</i> . Unpublished study. 2540p.	850.4150/Vegetative Vigor	Pass (05-Apr-2019)
50698722		Oxitec, Limited (2019) Published Literature Cited in Support of Documents Submitted for an Experimental Use Permit for Tetracycline-Repressible Transactivator Protein Variant (tTAV) and Related Genetic Material from OX5034 <i>Aedes aegypti</i> . Unpublished study. 2540p.	870.1100/Acute Oral Toxicity	Pass (05-Apr-2019)
50698722		Oxitec, Limited (2019) Published Literature Cited in Support of Documents Submitted for an Experimental Use Permit for Tetracycline-Repressible Transactivator Protein Variant (tTAV) and Related Genetic Material from OX5034 <i>Aedes aegypti</i> . Unpublished study. 2540p.	870.1300/Acute inhalation toxicity	Pass (05-Apr-2019)
50698722		Oxitec, Limited (2019) Published Literature Cited in Support of Documents Submitted for an Experimental Use Permit for Tetracycline-Repressible Transactivator Protein Variant (tTAV) and Related Genetic Material from OX5034 <i>Aedes aegypti</i> . Unpublished study. 2540p.	870.2400/Acute eye irritation	Pass (05-Apr-2019)
50698722		Oxitec, Limited (2019) Published Literature Cited in Support of Documents Submitted for an Experimental Use Permit for Tetracycline-Repressible Transactivator Protein Variant (tTAV) and Related Genetic Material from OX5034 <i>Aedes aegypti</i> . Unpublished study. 2540p.	870.2500/Acute dermal irritation	Pass (05-Apr-2019)
50698722		Oxitec, Limited (2019) Published Literature Cited in Support of Documents Submitted for an Experimental Use Permit for Tetracycline-Repressible Transactivator Protein Variant (tTAV) and Related Genetic Material from OX5034 <i>Aedes aegypti</i> . Unpublished study. 2540p.	880.1100/Product identity and composition	Pass (05-Apr-2019)
50698722		Oxitec, Limited (2019) Published Literature Cited in Support of Documents Submitted for an Experimental Use Permit for Tetracycline-Repressible Transactivator Protein Variant (tTAV) and Related Genetic Material from OX5034 <i>Aedes aegypti</i> . Unpublished study. 2540p.	880.1200/Description of starting materials, production and formulation process	Pass (05-Apr-2019)
50698722		Oxitec, Limited (2019) Published Literature Cited in Support of Documents Submitted for an Experimental Use Permit for Tetracycline-Repressible Transactivator Protein Variant (tTAV) and Related Genetic Material from OX5034 <i>Aedes aegypti</i> . Unpublished study. 2540p.	880.1400/Discussion of formation of impurities	Pass (05-Apr-2019)
50698723		Oxitec, Limited (2019) Standard Operating Procedures for Production of <i>Aedes aegypti</i> , OX5034. Project Number: GL/BR/00029/ED/2/B, GL/BR/00030/ED/3/B, GL/BR/00031/ED/2/B. Unpublished study. 161p.	880.1200/Description of starting materials, production and formulation process	Pass (05-Apr-2019)

